DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

September 15, 2014

I.E.M. GmbH
c/o Mr. Arne Briest
Regulatory Affairs
Cockerillstraße 69
52222 Stolberg
Germany

Re: K140928
Trade/Device Name: ABPM 7100 PWA with Hypertension Management Software Client Server 4.7
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive blood pressure measurement system
Regulatory Class: Class II
Product Code: DXN
Dated: July 11, 2014
Received: July 14, 2014

Dear Mr. Briest:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

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Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K140928

Device Name
ABPM 7100 used with the application software the Hypertension Management Software Client Server (HMS-CS)

Indications for Use *(Describe)*
The ABPM 7100 is an automated microprocessor controlled ambulatory blood pressure monitor (ABPM) which monitors, accumulates and stores: heart beat (rate), systolic and diastolic data of an individual adult patient (in the patient's environment) for a session which may last 24 hours.

The ABPM 7100 in combination with Hypertension Management Software Client Server (HMS-CS) provides a derived ascending aortic blood pressure waveform and a range of central arterial indices. Use of the Augmentation Index AIx only is restricted to patients of age 40 and above.

It is used with a standard cuff blood pressure measurement.

It is used in those patients where information related to the ascending aortic blood pressure is desired but in the opinion of the physician, the risk of cardiac catheterization procedure or other invasive monitoring may outweigh the benefits.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

510(k)	**ABPM 7100** **510(k) Summary**	

Section 06– Executive Summary

1. Submission Sponsor and Correspondent

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52222 Stolberg
Germany

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Contact: Mr. Arne Briest

Homepage: www.iem.de

FDA Establishment Registration #: 9617476

2. Date Prepared

April 4, 2014

3. Device Identification

Trade/Proprietary Name:	**ABPM 7100** used with Hypertension Management Software Client Server (HMS-CS)
Common/Usual Name:	Noninvasive blood pressure measurement system
Classification Name:	System, Measurement, Blood-Pressure, Non-Invasive
Classification Regulation:	CFR 87O.1130
Product Code:	DXN
Device Class:	Class II
Classification Panel:	Cardiovascular

4. Legally Marketed Predicate Device

K110603 **Mobil-O-Graph 24h PWA and HMS CS Version 4.3** by I.E.M. GmbH

5. Device Description:

The **ABPM 7100** consist of the following hardware:

- the **ABPM 7100** monitor
- the brachial blood pressure cuff

The **ABPM 7100** is available with three different cuff sizes (S, M, L, XL) to adapt to the patient's arm size.

Patient data is stored in the device's memory. The data can then be transmitted to a computer in the physician's office via Bluetooth and Cable. The recordings are displayed for the evaluation by the health professional by the application of the Hypertension Management Software Client Server ("HMS CS").

The **ABPM 7100** is used together with the application software the Hypertension Management Software Client Server (HMS-CS 4.7-US) as a system.

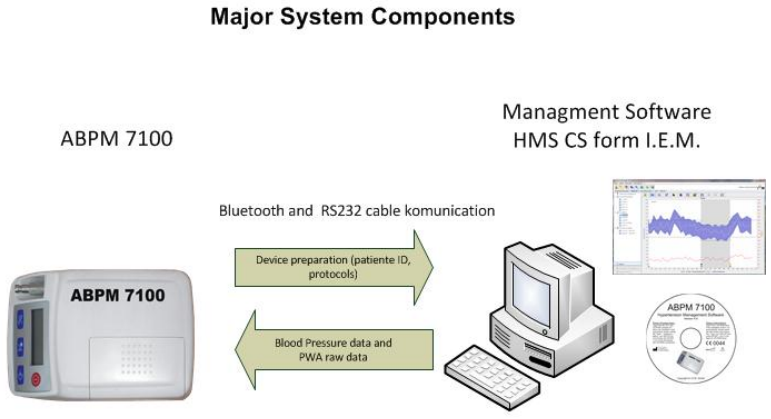

Figure 06-1 Major System Components

6. Indications for Use:

The **ABPM 7100** is an automated microprocessor controlled ambulatory blood pressure monitor (ABPM) which monitors, accumulates and stores: heart beat (rate), systolic and diastolic data of an individual adult patient (in the patient's environment) for a session which may last 24 hours.

The **ABPM 7100** in combination with Hypertension Management Software Client Server (HMS-CS) provides a derived ascending aortic blood pressure waveform and a range of central arterial indices. Use of the Augmentation Index Aix only is restricted to patients of age 40 and above.

It is used with a standard cuff blood pressure measurement.

It is used in those patients where information related to the ascending aortic blood pressure is desired but in the opinion of the physician, the risk of cardiac catheterization procedure or other invasive monitoring may outweigh the benefits.

7. Substantial Equivalence Discussion

The following table A and B compares the **ABPM 7100** to the predicate device with respect to technological characteristics and principles of operation, providing more detailed information regarding the basis for the determination of substantial equivalence.

The intended use of both the **ABPM 7100** and the predicate are identical.

Device Comparison Summary:

Table A – Device Comparison Table

Manufacturer	**I.E.M. GmbH**	**I.E.M. GmbH**
Trade name	**ABPM 7100** (in combination with Hypertension Management Software Client Server (HMS-CS 4.7-US))	**Mobil-O-Graph** (24h PWA in combination with Hypertension Management Software Client Server (HMS-CS 4.3)
510(k) Number	TBD	K110603
Product Code	DXN	DXN
Regulation Number	870.1130	870.1130
Class	II	II
Regulation Name	Non-Invasive blood pressure measurement system	Non-Invasive blood pressure measurement system
Sterile	non-sterile	non-sterile
Single-Use	NO	NO
Power	2 alkaline 1,5 V batteries (AA) or rechargeable 1.2 V (AA)	2 alkaline 1,5 V batteries (AA) or rechargeable 1.2 V (AA)
Cuffs	Identical	
Communication: Bluetooth, USB connector, Infrared, Serial RS232	YES	YES
Latex free	YES	YES
Complies with ISO 10993-1	YES	YES
Electrical safety testing passed	YES	YES

Table B – Software Comparison Table

Manufacturer	**I.E.M. GmbH**	**I.E.M. GmbH**
Trade name	**HMS-CS 4.7 US**	**HMS-CS 4.3 US**
510(k) Number	TBD	K110603
Product Code	DXN	DXN
Regulation Number	870.1130	870.1130
Class	II	II
Regulation Name	Non-Invasive blood pressure measurement system	Non-Invasive blood pressure measurement system
Patient management	List, select from list, modify, delete, import, export	List, select from list, modify, delete, import, export
Overview of measurement data	Overview of all measurements with date/time and type	Overview of all measurements with date/time and type
Print report with patient data, graph and comments	YES	YES
Common database for the data collected by the compatible devices	YES	YES
Compatibility with other devices	HMS-CS may only be used in the United States with devices currently cleared by the FDA.	HMS-CS may only be used in the United States with devices currently cleared by the FDA.

8. Non-Clinical Performance Data

As part of demonstrating safety and effectiveness of **ABPM 7100** and in showing substantial equivalence to the predicate devices that are subject to this 510(k) submission, I.E.M. completed a number of tests.

Performance testing

The **ABPM 7100** is substantially equivalent to the predicate device (K110603) - **Mobil-O-Graph** 24h PWA used in combination with Hypertension Management Software Client Server (HMS-CS 4.3). The hardware, both electrical and non electrical, is identical.

The Electrical Safety test reports presented for the **Mobil-O-Graph** 24h PWA are equally applicable to the ABPM 7100. The tests were performed according to IEC 60601-1 Medical electrical equipment – Part 1: General requirements for safety and IEC 80601-2-30 Medical Electrical Equipment - Part 2-30: Particular Requirements For The Basic Safety And Essential Performance Of Automated Non-Invasive Sphygmomanometers.

Software testing

The HMS CS application software was developed and tested according to written internal Procedures that implement the processes described in FDA guidance "General Principles of Software Validation", FDA Guidance for the "Content of Premarket Submissions for Software Contained in Medical Devices";- and Risk Management was conducted in accordance with ISO 14971.

All required software testing was completed as part of the software verification and validation and all tests passed.

Electrical safety

General requirements for safety were tested according to IEC 60601-1 Medical electrical equipment – Part 1: General requirements for safety.

Electromagnetic compatibility

Electromagnetic compatibility testing covering the emission and immunity of the device was tested according to IEC 60601-1-2 Medical electrical equipment – Part 1-2: General requirements for safety – Collateral standard: Electromagnetic compatibility – Requirements and tests.

Biocompatibility

All components (brachial blood pressure cuff) in contact with the patient are unchanged from the predicate device (K110603) - **Mobil-O-Graph** 24h PWA in combination with Hypertension Management Software Client Server (HMS-CS 4.3).

Summary

The **ABPM 7100** meets all the stated requirements for overall design, performance, biocompatibility, and electrical safety. Testing according to written protocols confirms that the design outputs meet the design inputs.

The **ABPM 7100** passed all testing stated above.

The **ABPM 7100** complies with the applicable voluntary standards for biocompatibility, electrical safety and electromagnetic compatibility. The device passed all the testing in accordance with national and international standards.

9. Clinical Performance Data

There was no clinical testing required to support the medical device as the indications for use is equivalent to the predicate device. These types of devices, including the predicate devices, have been on the market for many years with a proven safety and efficacy for the use of the device. The non-clinical testing performed with **Mobil-O-Graph** 24h PWA (predicate device) remain applicable for the **ABPM 7100**.

10. Statement of Substantial Equivalence

By definition, a device is substantially equivalent to a predicate device when the device has the same intended use and the same technological characteristics as the previously cleared predicate device. Or the device has the same intended use and different technological characteristics that can be demonstrated that the device is substantially equivalent to the predicate device, and that the new device does not raise different questions regarding its safety and effectiveness as compared to the predicate device.

It has been shown in this 510(k) submission that the difference between the **ABPM 7100** together with the HMS CS 4.7-US application software and the predicate devices do not raise any questions regarding its safety and effectiveness.

Performance testing and compliance with voluntary standards, demonstrate that the **ABPM 7100** and the HMS CS 4.7-US application software are substantially equivalent to the relevant aspects of the predicate devices in terms of design, components, materials, principals of operation, biocompatibility, performance characteristics, and intended use.

The **ABPM 7100** and the HMS CS application software, as designed and manufactured, are determined to be substantially equivalent to the referenced predicate devices.